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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,192	06/16/2005	Gordon Feingold	09138.0074	2551

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EXAMINER	
GORDON, BRIAN R	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,192	FEINGOLD ET AL.	
	Examiner	Art Unit	
	Brian R. Gordon	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *358-385* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *358-385* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. In view of the cancellation of claims 318-357 in the response filed July 22, 2010, all previous rejections have been withdrawn. However, it should be noted that some of the same previous rejections are applicable to the new claims. The newly submitted claims are addressed herein below.

It should be noted that applicant has added all new claims. The examiner previous requested that applicant specify where each amendment and new claims are supported within the specification, but applicant has failed to do so. To ensure that no new matter has been incorporated within the claims, the examiner hereby requests applicant or provide for where each of the new claims are supported within the originally filed specification. The claim language is not consistent with the specification. For example, the examiner fails to locate the terms "commands" and "queries" in the specification. Considering the length of the specification it is more difficult for the examiner to determine if newly added claims are supported therein.

As to Lemme 2002/0110494, applicant asserts Lemme does not suggest inserting at least one reagent or a sample without interrupting dispensing. The examiner disagrees. As previously stated in the previous Office Action, the reagent fluid dispensers 12 of Lemme operate independently. As such, each of the reagent fluid dispensers can be removed from a respective receptor without interrupting the dispensing from another dispenser that is located at the dispensing position.

The claims are rejected as given herein.

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 358-385 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 358 and 372, it is unclear how dispensing reagents with a robotic head relates to processing a first sample. Where are the dispensing reagents dispensed? There is no requirement for the reagents to be dispensed to, mixed with, etc. with the first sample.

Furthermore while it is claimed that the processing occurs with the robotic head it is not specified where the processing occurs. The claim does not preclude the robotic head from having the ability to move or extend beyond the boundaries of what applicant considers as the stainer. It is conventionally known the robotic arms/heads can have wide ranges of motion. As such, it is foreseeable that the robotic head is not limited to movement and being operated in the at least one stainer.

It should be noted there is no requirement for the robotic head to be an element of the stainer. The robotic head can be a separate element of a different apparatus that used in conjunction with the stainer.

It is unclear how one can begin processing of the second sample when there is no requirement that a second sample be present in the stainer. It should be noted that the claims recite "inserting at lest one reagent in the stainer **or** a second sample into the stainer..." Therefore, one can elect to simply insert a reagent in the stainer without a second sample being present. The claim as drafted does not clearly reflect that processing of a second sample only occurs when a second sample is inserted.

. The term stainer has not been defined or restricted to a specific structure. Any device capable of dispensing fluids to slides or any other objects/substrates can be considered a stainer.

As to claim 362 it is unclear what is meant by "associated with". The phrase does not require and structural relationship or connection. Anything can be classified as broadly associated with something else. Where is the database located?

As to claims 363 and 375, it is unclear what the operations are related to. Purging and compaction of what? Database back-up operations of what?

As to claims 364-365, 377-378 it is unclear who or what runs the diagnostic tests and receives the diagnostic information. What are diagnostic tests run on? What is diagnosed? What are the diagnostic tests related to? What is tested?

As to claims 364 and 378, it is unclear what is meant by retrieving diagnostic information. Does this mean results are sent to a specific location (such as computer,

display, printer, etc.)? Does this mean an operator manually records results? Does this mean an operator gathers information for running the tests? Does this mean a computer or other device communicates with some other device/database and electronically collects the information from there?

As to claim 365 and 378, it is unclear what is meant by "actively exercise components". It should be noted that no prior claims require or state the stainer has any specific components on it.

It should be noted that the steps of claims 366, 368-371, 379, and 383-385 are not restricted be performed by any specific device or structure. An operator can perform these steps (operations) by observing with one's own eyes, mentally. One can troubleshoot, monitor, encrypting, and estimate within ones own mind. Mental, abstract steps are not patentable.

As to claims 367 and 380, what provides for the notification?

As to claim s 368 and 382, it should be noted that the claims are not restricted to any specific operations. The term "operations" is very broad can be any action directed to the stainer. For example, merely adjusting the position of the stainer can be considered an operation.

As to claim 376, is not further limiting of the method of claim 372. Firstly, it should be noted that the step is conditional and only occurs if there is a malfunction. Secondly, it is unclear where the second stainer is located. It has not been established that a second stainer is included in the structure required for the method.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 358-385 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. See Response to Arguments.

Applicant has amended the claims, but failed to specify where the amendments are supported within the specification. The examiner fails to locate where the invention as claimed as located and more specifically the amendments. It is hereby requested applicant specify where the claim amendments are supported within the originally filed specification.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 358-385 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lemme et al. US 2007/0086917.

Lemme et al. disclose an apparatus and methods for automatically staining or treating multiple tissue samples mounted on slides. To stain multiple slides as quickly as possible the instrument should process the slides simultaneously. This is feasible

given that most of the time slides are just incubating, thus freeing up time to perform the washing, reagent application and other functions on other slides. (paragraph 0009).

Apparatus 10 functions as one component or module of a system 12 (FIG. 2) which also comprises a host computer 14 preferably a personal computer, monitor 16, keyboard 18, mouse 20, bulk fluid containers 22, waste container 23 and related equipment. Additional staining modules or other instruments may be added to system 12 to form a network with computer 14 functioning as a server. (paragraph 0039).

The apparatus includes nozzle support 100 and probe arm 400 including two reagent transfer probes 402 or 404 (robotic arms).

Slide drawer 34 is divided into thirty-five equal pie-shaped sections 70. Thirty of the pie-shaped sections 70 are occupied by slide platforms 50 while the five remaining pie-shaped sections 70A (FIG. 4) at the rear of the drawer are devoid of slide platforms 50. In other words, a row of thirty slide platforms 50 are radially mounted on drawer 34 and evenly spaced from one another, except at the ends of the row. (paragraph 0044).

The device also includes reagent bottles (302, 304). The slides and reagent bottles can be changed without interrupting dispensing of materials.

While the reference does not specify commands are sent over a network, the examiner that it is inherent that commands and other information are sent over the network of Lemme et al.

If it is not considered inherent, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the network as means for operating the device of Lemme et al.

As stated in the prior Office Action, it should be recognized that bridges (and other components, such as servers, routers, gateways, etc.) are conventionally well known equipment employed within the configuration of networks to allow for communication between network devices (computers/controllers). Furthermore sending, relaying, and receiving commands, instructions, protocols over computer networks are conventionally known.

The claims do not appear to claim any novel aspects of the use of computer networks. Computer networks are staple components of today's society. It is readily known that WAN and LAN networks are employed for sending various types of data (including encrypted, i.e. internet or intranets) in various environments ranging from private homes, businesses, hospitals, laboratories, etc. The use of networking and backup hardware/software is inherent in a network configuration such as that taught by Lemme et al. (see also Showalter, provisional application 60/487,998, prior art submitted by applicant).

It is readily known that computers are equipped to be included within networks. One can go to "network connections" on a PC and view bridge settings and other connections. Furthermore it is known that PCs are equipped with web browsing and troubleshooting/diagnostic software.

9. Claims 358-385 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemme et al. US 2002/0110494 A1.

Lemme et al. disclose a method and apparatus for an automated biological reaction system. In the processing of a biological reaction system, there is a need for

consistently placing an amount of fluid on a slide. In order to operate the automated biological reaction system more reliably, the system is designed in modular pieces with higher functions performed by a host device and the execution of the staining operations performed by remote devices. Also, to reliably catalog data which is used by the automated biological reaction system, data is loaded to a memory device, which in turn is used by the operator to update the operator's databases. The generation of the sequence of steps for the automated biological reaction device based on data loaded by the operator, including checks to determine the ability to complete the run. (Abstract).

FIG. 5A, shows a block diagram of the automated biological reaction system 150. The automated biological reaction system 150 is segmented into a host device 32 (server), which includes a typical personal computer, and at least one remote device 166, which includes the automated biological reaction device in FIGS. 2 and 6A. In the preferred embodiment, there are up to eight remote devices 166 which communicate with the host device 32. Each remote device 166 on the network has a unique address so that each remote device 166 may be identified and individually controlled by the host device 32. As described subsequently in FIG. 5B, the automated biological reaction system 150 can support up to eight remote devices 166 due to the 3 bits (values 0-7) dedicated to the addressing of the remote devices 166. A rotary switch is provided on the remote device 166 to allow for the identification and the changing of the 3 bit address for each remote device 166. All host messages include this address in them, as described subsequently in FIG. 5B. However, the number of remote devices 166 can be smaller or larger than eight, depending on the capacity requirements or practical

limitations of the laboratory in terms of space. Moreover, the remote devices 166 may be immunohistochemistry staining modules, another type of instrument that performs a different type of staining, or another type of medical testing device. (paragraph 105).

Communication between the host device 32 and the remote devices 166 is accomplished using a serial RS-485 link, which serves as a network, that supports one host and up to 32 remotes at one time. In the preferred embodiment, addressing of the remote devices 166 allows up to 8 remote devices to communicate with the host at one time. The RS-485 link has at least two pairs of lines for communication, one pair for transmitting and one pair for receiving. The remote devices 166 which are connected to the network "hear" the host messages but do not "hear" other remote messages. In the preferred embodiment, all communications begin with a host message, followed a short time later by a response by a remote device 166 if present. (sending/receiving) If the host device 32 sends a message and there is no remote device 166 to respond to it, the host device 32 times out. In this manner, the communication provides a simple, collision-free link between the host device 32 and the remote devices 166. In an alternative embodiment, the remote devices 166, in addition to communicating with the host device 32, address each other. For example, the remote devices 166 address each other using the unique 3 bit address, sending information about staining runs, which are described subsequently. (paragraph 106).

The user database, which is required by the regulations, contains various tables including the registration, receive and quality control tables for use by the operator. Within each of the registration, receive and quality control tables, there are five different

types of categories: (1) antibodies; (2) reagents; (3) kits; (4) consumables, and (5) control slides. (paragraph 226).

The claims do not appear to claim any novel aspects of the use of computer networks. Computer networks are staple components of today's society. It is readily known that WAN and LAN networks are employed for sending various types of data (including encrypted, i.e. internet or intranets) in various environments ranging from private homes, businesses, hospitals (see paragraph 240), laboratories, etc. The use of networking and backup hardware/software is inherent in a network configuration such as that taught by Lemme et al. (see also Showalter, provisional application 60/487,998, prior art submitted by applicant).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, 1st Fri. Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian R Gordon/
Primary Examiner
Art Unit 1797